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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:
A61M 5/28	A1	WO 93/09825
		(43) International Publication Date: 27 May 1993 (27.05.93)

(21) International Application Number: PCT/CA92/00495

(22) International Filing Date: 13 November 1992 (13.11.92)

(30) Priority data:
791,399 14 November 1991 (14.11.91) US

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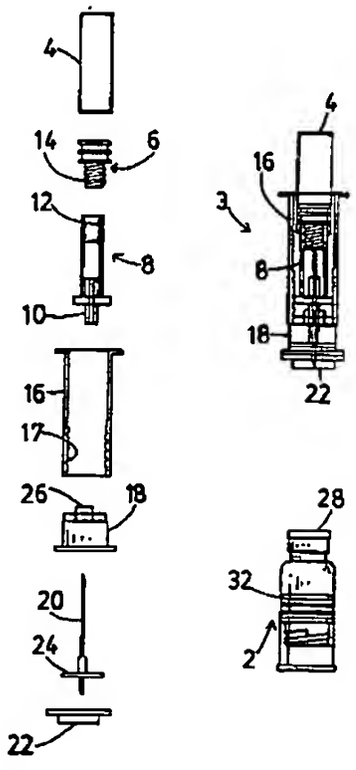
(81) Designated States: AU, BB, BG, BR, CA, CS, DE, FI, GB, HU, JP, KR, NO, RO, RU, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SYRINGE

(57) Abstract

A prefilled syringe system is provided for two component pharmaceuticals, which is a combination of a first subassembly consisting of a capped bottomless pharmaceutical vial (2) containing a first component and closed at its bottom end by a piston (32) which can be connected to a plunger (16) and a second subassembly (3) consisting of a shell (4) containing a second component and closed by a further piston (6) and located in telescopable relationship with the plunger, a cap (18) which can be forced onto the cap (36) of the bottomless vial, and a double ended needle (320) or a functionally equivalent cannula assembly which is caused to pierce both pistons as the assemblies are connected by forcing the cap (18) onto the bottomless vial, thus placing the vials in communication. The shell vial (4) is pressed towards the bottomless vial (2) to express its contents into the latter, and the plunger (16) and shell vial (4) are then removed so that the cap (18) and needle (20) are left connected to the bottomless vial (2) and the plunger (16) may be connected to the piston (32) of the bottomless vial to convert it into a syringe. The shell vial may telescope either over or within the plunger. In the first case, the plunger acts to operate the piston of the shell vial during expression of its contents, whereas in the latter case a separate component (8) is required for this purpose.



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SYRINGE

TECHNICAL FIELD

This invention relates to prefilled syringe systems for the packaging of pharmaceutical preparations in dosage form, and more particularly to systems in which two components of a preparation, one of which is normally a diluent or solvent, must be stored separately and only admixed immediately prior to administration.

BACKGROUND ART

Our United States Patent No. 5,137,511 describes several syringe systems for the packaging of two component pharmaceutical preparations, of which the system shown in Figures 11 and 12 is presently the most preferred. This system stores a solvent or diluent component in a specially formed capsule 14 which is described in detail in that patent.

Shell vials are however a well known and widely available packaging for pharmaceutical diluents. A shell vial differs from a conventional pharmaceutical or serum vial in that it has no neck. Instead the top of the vial is of the same diameter as the remainder of the cylindrical side wall of the vial, and is closed by a piston quite similar to that utilized by the present applicant to close the bottom of its bottomless vial as described in U.S. Patent No. 5,137,511.

DISCLOSURE OF INVENTION

I have now found that the construction shown in this patent can be advantageously modified to utilize known shell vials in place of the capsule 14.

According to the invention, a prefilled syringe system for two component pharmaceuticals is provided, as set forth in the appended claims 1-5.

BRIEF DESCRIPTION OF DRAWINGS

Preferred embodiments of the invention are described with reference to the accompanying drawings, in which:

Figures 1A-1I are elevations illustrating successive stages in the assembly and preparation of use of a first embodiment of the invention, it being assumed for ease in illustration that most components other than those of rubber or metal are transparent; and

Figures 2A-2G are elevations illustrating successive stages in the assembly and preparation for use of a second embodiment of the invention.

BEST MODES FOR CARRYING OUT THE INVENTION

Figure 1A shows an exploded view of the components of a separately assembled and sterilized unit 3 (see Figure 1B) for use in conjunction with a filled and capped vial 2 generally similar to that shown in Figure 12 of U.S. Patent No. 5,137,511. The unit 3 comprises a shell vial having a cylindrical body 4 closed at one end, and a piston 6 closing its other end to enclose a quantity of pharmaceutical diluent. A moulded plastic tubular adaptor component 8 has a tubular connector 10 at one end similar to the connector element 70 of U.S. Patent No. 5,137,511, and an internal thread 12 within its other end forms a coupling engaged with an external thread on a extension 14 forming a coupling configuration on the piston 6. A tubular plunger 16 has an internal thread 17 which can provide a coupling to an integral extension or other coupling configuration on a piston 32 of the vial 2. This plunger and a cap 18 are similar to corresponding parts shown in the U.S. patent. The unit further includes a cannula needle 20, and a protective cap 22 which closes the open end of the cap 18 to maintain sterility and provide protection of the needle during storage. The cap 22 is

removed immediately before use (see Figure 1C). The needle 20 is of the double ended type, and is located beneath the cap 18 by a flange 24. A connector 26 on the cap engages the connector 10 on the adaptor component 8 in the same way as the connector 27 engages the connector 70 in Figure 12 of U.S. Patent No. 5,137,511, so that one end of the needle 20 passes through the adaptor towards the piston extension 14, as seen in Figure 1B.

After the cap 22 has been removed (Figure 1C), as well as a flip-off protective cover 28 on the cap 30 of the vial 2, which protects a rubber closure of the vial held in place by the cap 30 (Figure 1F), the unit 3 is pressed onto the vial 2 (Figure 1F) so that the cap 18 is pressed over the cap 30 of the vial 2 so that the lower end of the needle 20 pierces a rubber closure of the vial 2. At the same time, the flange 24 is pressed upwardly within the cap 18 and causes the upper end of the needle 20 to penetrate a septum within the piston 6.

The shell vial 4 is then pressed downwardly (Figure 7F) expelling its contents through the needle 20 into the vial 2. If necessary, the piston 32 within the vial 2 is positioned higher in the vial than normal so that it can be displaced downwardly to make room for the contents of vial 4 (see Figure 1G).

At this point, the assembly 3, with the exception of the cap 18 and the needle 20, is pulled away from the vial 2 by gripping the plunger 16 leaving the cap and needle in place on the vial (Figure 1G). The thread 17 of plunger 16 is then screwed onto the piston 32 of the vial 2 (Figure 1H) to form a syringe 34 (Figure 1I).

In the embodiment just described, the shell vial is dimensioned so as to fit within the tubular plunger. An

alternative embodiment is shown in Figures 2A-G in which the shell vial 4 is dimensioned so that the tubular plunger 16 has an external diameter less than its internal diameter. The same reference numerals are used to denote those components of this embodiment which are similar to those of the previous embodiment, and only the differences will be described. In this instance, the plunger 16 fulfils the functions of the adaptor 8, the screw threads on extensions of the pistons 6 and 32 being similar except that the thread 14 on piston 6 may be longer. The plunger 16 is a press fit on the connector 26 on the cap 18, which in this case is formed with a skirt 36 which fits over the top portion of the vial 2 and also provides a finger grip 38. The entire unit 3 (see Figure 2C) is assembled into a tubular sleeve 40 (Figure 2B) which together with the cap 22 maintains sterility of the unit during storage, and also facilitates preparation of the syringe. The vial 4 is a press fit within the upper end of the sleeve 40. After removal of the cap 22, the unit 3 is applied to the vial (Figure 2D) as in the previous embodiment, and the sleeve 40 is pulled downwardly (Figure 2E). As before, this forces the cap 18 onto the cap 30 of the vial, causing the needle 20 to pierce both the closure of the vial 2 and the piston 6 of the shell vial 4, and further downward movement of the sleeve 40 forces the contents of the shell vial into the vial 2. At this point the sleeve 40 is rotated to unscrew the piston 6 of the shell vial 4 from the plunger 16 (Figure 2F) which is then transferred to the piston 32 to complete the syringe.

It should be understood that the sleeve 40 could be omitted, although it is a convenience for packaging and manipulating the syringe, in which case the vial 4 would be manipulated directly rather than through the sleeve 40.

Variations in the above embodiments are possible. For some applications of the syringe, it may be desired to replace the needle 20 by some other cannula arrangement when the syringe is used, in which case a single ended needle may be located in the assembly 3 so that it will be forced upwardly as the cap 18 is forced onto the vial 2 (the cap in this case will have an internal cannula to pierce the closure of the vial), but will be retained within the shell vial when the latter is removed during preparation of the syringe. If a double ended needle 30 is used, in combination with a cannula, venting of the vial 2 to permit escape of air displaced by the contents of the shell vial 4 becomes possible, in a manner similar to that shown in Figure 16 of U.S. Patent No. 5,137,511.

CLAIMS:

1. A prefilled syringe system for two component pharmaceuticals, characterized by the combination of first and second subassemblies, of which the first subassembly comprises a bottomless pharmaceutical vial (2) having a filling neck, a penetrable closure retained on said neck by a first annular cap (30), and an open bottom end hermetically closed by a first piston (32) with a downwardly facing coupling configuration within the vial, and the second subassembly (3) comprises a shell vial (4) having an open end closed by a second piston (6), a tubular plunger (16) concentric and in telescoping relationship with the shell vial, the plunger having a coupling (17) at one end for subsequent coupling to the coupling configuration (14) of said first piston (32), a second cap (18) releasably connected to said plunger which can be force fitted to said first cap (30), and cannula means (20) projectable by force fitting of said first cap (30) to said second cap (I8) to penetrate both said penetrable closure and said second piston (6) to place said bottomless vial (2) and said shell vial (4) in fluid communication through said cannula means (20) whereby fluid from the shell vial is transferred to the bottomless vial upon telescoping said shell vial relative to said plunger (16).

2. A syringe system according to claim 1, characterized in that the shell vial (4) is of a diameter to telescope into said plunger (16), and adaptor means (8) are provided in said second subassembly extending between said second cap (18) and a coupling configuration (14) on said second on said second piston (6) to maintain the position of the latter during telescoping of the shell vial relative to the plunger.

3. A syringe system according to claim 1, characterized in that the shell vial (4) is of a diameter to telescope around said plunger (16), and said means (17) on the plunger for coupling to the coupling configuration of the first piston (32) are initially coupled to coupling means (14) on the second piston (6).

4. A syringe according to claim 3, characterized in that the components of the second subassembly (3) are assembly within a tubular housing (40), and the shell vial (4) is a press fit within the tubular housing.

5. A syringe system according to any one of claims 1-4, characterized in that the cannula means (20) is a double ended needle, with a flange (24) to control its longitudinal position received within the second cap (18).

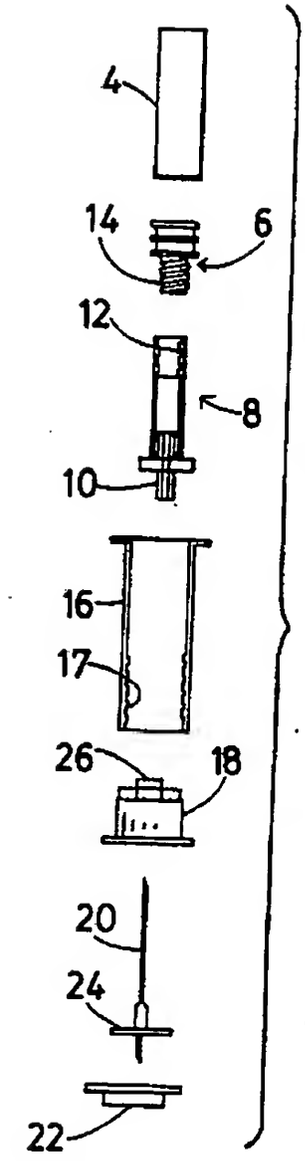

FIG1A

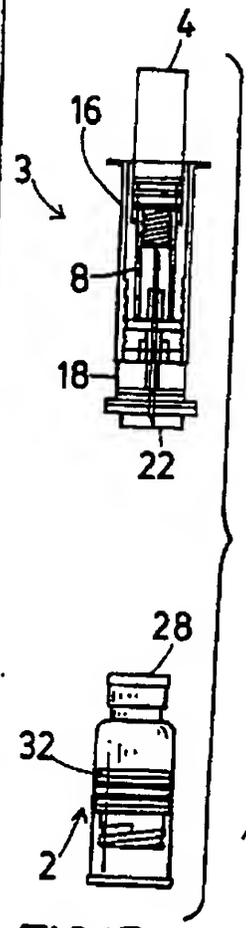

FIG.1B

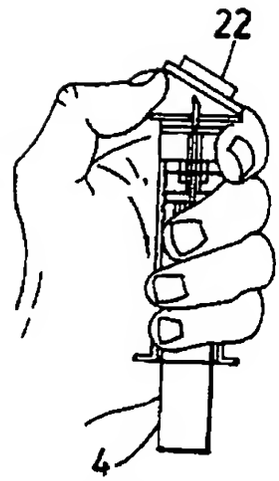

FIG.1C

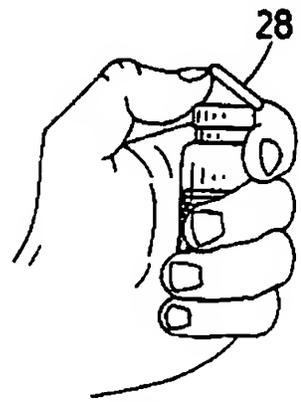

FIG.1D

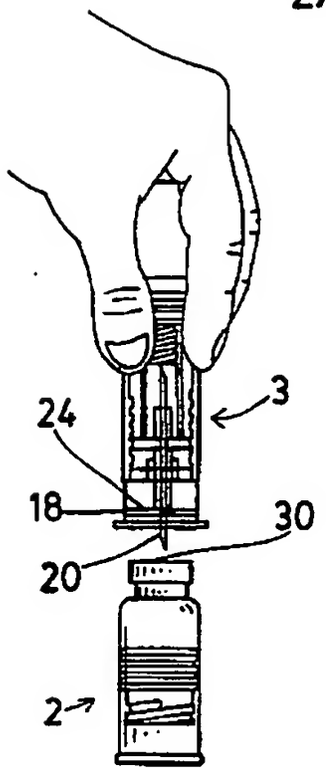

FIG.1E

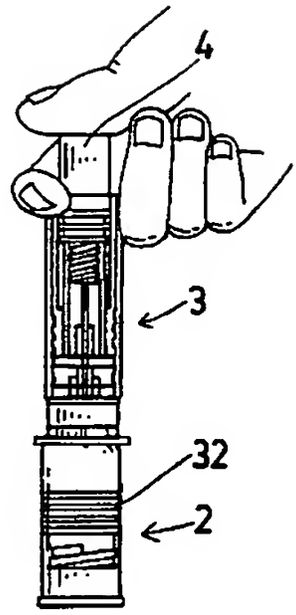

FIG.1F

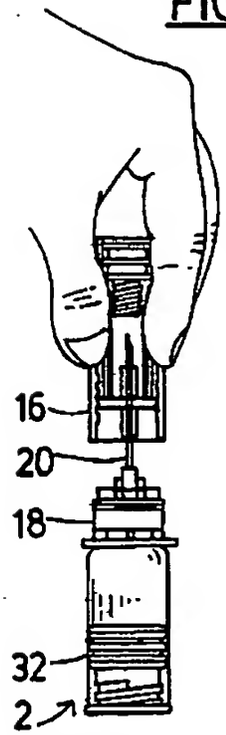

FIG.1G

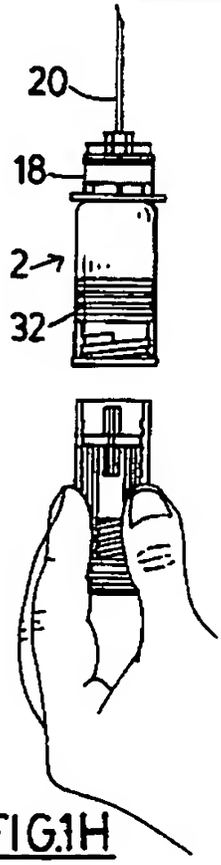

FIG.1H

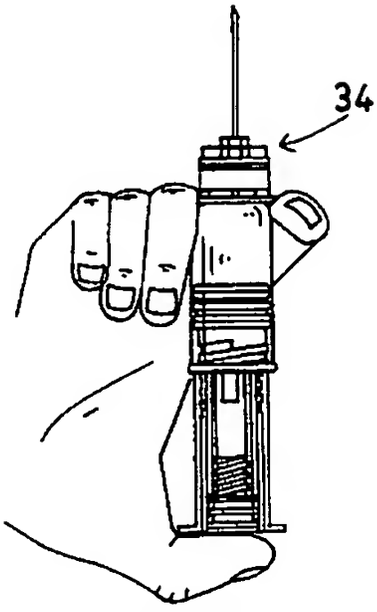

FIG.1I

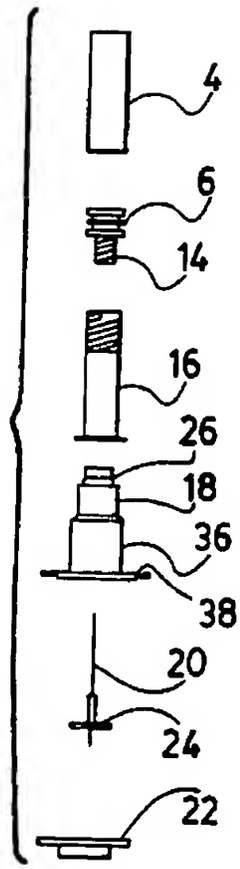

FIG. 2A

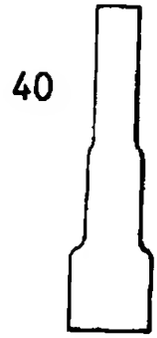

FIG. 2B

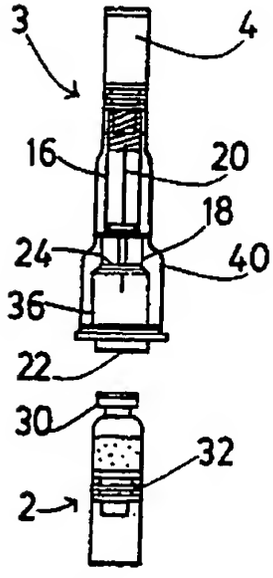

FIG. 2C

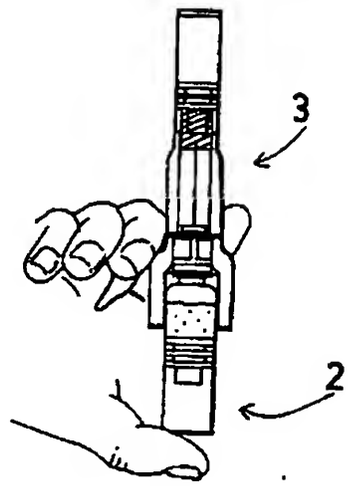

FIG. 2D

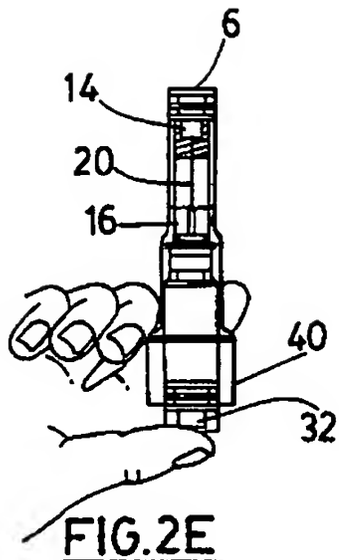

FIG. 2E

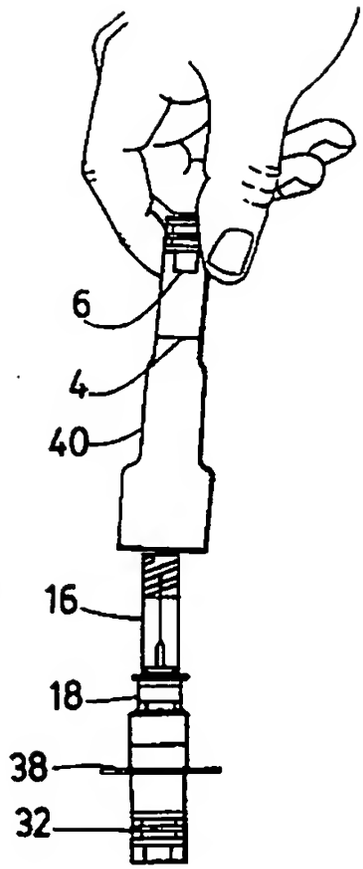

FIG. 2F

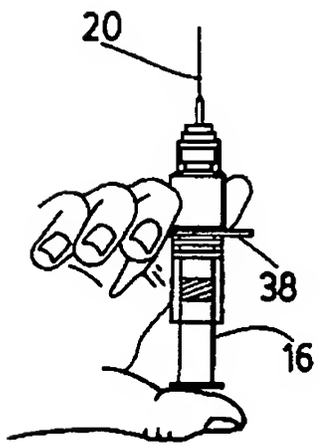

FIG. 2G

INTERNATIONAL SEARCH REPORT

International Application No PCT/CA 92/00495

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M5/28

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M ; A61J

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A A,P	EP,A,0 298 585 (DUOJECT MEDICAL SYSTEMS INC) 11 January 1989 see the whole document & US,A,5 137 511 (REYNOLDS) cited in the application	1,2,5
A	DE,A,1 766 151 (FARBENFABRIKEN BAYER AG) 3 June 1971 see claims; figure 2	1
A	US,A,4 424 057 (HOUSE) 3 January 1984 see claims; figures	1
A	US,A,4 014 330 (GENESE) 29 March 1977 see claims; figures	1

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
11 MARCH 1993	16. 03. 93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	SEDY R.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

CA 9200495
SA 66152

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